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News

West Virginia Board of Pharmacy

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Beware of Illegal Internet Pharmacy Schemes

The governor's substance abuse legislation, SB 437, became effective June 8, 2012. Included in the legislation is a clarification of the law in WV Code §30-5-3(g). This subsection was designed to curb illegal prescriptions for Internet pharmacy without a legitimate doctor-patient relationship, and the new clarification further nails this down given the expansion of such operations across the country. That section, as amended, states in relevant part:

> No pharmacist may compound or dispense any prescription order when he or she has knowledge that the prescription was issued by a practitioner without establishing a **valid practitioner-patient relationship. An online or telephonic evaluation by questionnaire, or an online or telephonic consultation, is inadequate to establish a valid practitioner-patient relationship.**

This provision, of course, is subject to some exceptions for cross-coverage and the like. The language about online or telephonic evaluations by **questionnaire** has existed in the code for many years, and the modification this year was simply to add the language about online or telephonic **consultations.** This is a minor, but needed, clarification to guard against potential arguments trying to get around the requirement. In short, a prescriber has to have a valid relationship with the patient, which is going to require some face-to-face interaction and examination to establish it in the first place. If the patient is in one state, and the prescriber in another, that should be a red flag for a pharmacist to inquire as to whether a proper practitioner-patient relationship exists.

The West Virginia Board of Pharmacy has recently worked with a couple of situations where illegal Internet operations were working in West Virginia. The situations were resolved amicably with the West Virginia pharmacies and personnel, without discipline by the Board, based upon them voluntarily ceasing the practice. If you are involved in a situation like this, please report it to the Board and stop immediately. If the Board otherwise learns of more situations like this, future substantiated cases will likely result in discipline.

Expansion of Pharmacist Immunizations

The Board of Pharmacy went through joint rulemaking with the Board of Medicine and Board of Osteopathy to amend Rule 15-12-2.2 to allow for four more vaccines that pharmacists can administer. You can now administer flu; pneumonia; Hepatitis A; Hepatitis B; Herpes Zoster; and Tetanus, Tetanus-Diphtheria, and Tetanus-Diphtheria-Pertussis vaccines. You do not have to have a prescription; you can follow the Centers for Disease Control and Prevention protocols. Of course, if you receive a prescription, you can follow it if you believe it is an appropriate prescription. The only other change is to require by rule for reporting any adverse events to the federally created and maintained Vaccine Adverse Event Reporting System (VAERS), with a copy sent to the Board of Pharmacy (§15-12-6.4). See *http://vaers.hhs.gov/index* for reporting to VAERS. This will help the Board deal with any adverse events on a state level, and provide data to the Boards of Medicine and Osteopathy about the programs offered through pharmacists.

Daily Reporting to CSMP; Counseling Offer Required on Pseudoephedrine Sales

The governor's substance abuse bill, SB 437, became effective June 8, 2012. Among other things, it made changes to the West Virginia Controlled Substances Monitoring Program (CSMP), and to the Methamphetamine Laboratory Eradication Act. These new provisions place added requirements on pharmacies and their staffs.

- *Daily Reporting to the CSMP:* Regarding the CSMP, among many other things, the new law states that the Board may require reporting of all dispensings of Schedule II-IV controlled substance prescriptions to the CSMP within 24 hours. As such, the Board prepared emergency rules that modified Series 8 of the rules, to require that dispensers report their dispensings of controlled substances to the

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DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

- the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
- the prescription contains all the information required by 21 CFR §1306.05; and
- the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at *www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.*

Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at *www.fda.gov/Safety/Recalls/ucm289770.htm.*

Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

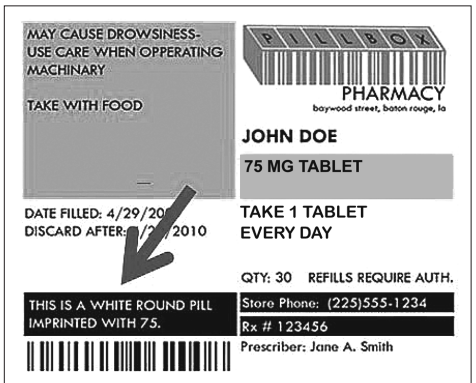
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it's based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.



With so much information on prescription labels such as patient and doctor name, drug name, instructions, and warnings – this added information can easily be missed. But it's important, so look for it and put it to use!

FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that "current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in

serious harm to patients." FDA reports that the agency is aware of promotions and sales of unapproved injectable cancer medications directly to clinics in the US and that the medications were likely administered to patients. Examples of products include unapproved versions of FDA-approved medications such as Faslodex® (fulvestrant), Neupogen® (filgrastim), Rituxan® (rituximab), and Herceptin® (trastuzumab). FDA stresses the risks to patients when such unapproved medications are used. The agency outlines several steps health care providers should take to ensure patient safety:

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.
2. Determine if the medication you have received is FDA-approved by checking the Orange Book or searching the Drugs@FDA database.
3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.
4. Carefully inspect the product and packaging and be alert for signs that the product is not FDA approved, such as if the packaging looks different or the dosing recommendations are unfamiliar.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, *www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.*

Additional details are provided in an FDA Drug Safety Communication, available at *www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf.*

Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become "increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV)." The notice explains that regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed. CDC provides the following recommendations to help protect patient safety:

- Insulin pens containing multiple doses of insulin are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- Insulin pens should be clearly labeled with the person's name or other identifying information to ensure that the correct pen is used only on the correct individual.
- Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

The notice may be downloaded from the CDC Web site at *www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf.*

US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice,* prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

- Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.
- Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.
- Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that "one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models." The report may be downloaded from the US PHS Web site at *www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf.*

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CSMP within 24 hours of the dispensing (48 hours if done by mail). It also requires filing "zero" reports if you do not have any dispensings within 24 hours of the prior reporting, and do not have a waiver from reporting (such waiver is available to those dispensers who do not stock any Schedule II-IV controlled substances).

- *Counseling Offer Required for Over-the-Counter PSE Sales:* The new law also changes several things with sale of methamphetamine-precursors – pseudoephedrine or ephedrine containing products (PSE). In addition to moving to the national real-time point-of-sale database commonly referred to as National Precursor Log Exchange or MethCheck by January 1, 2013, the new law limits the amount of grams a person may purchase in any 30-day period to 7.2 grams, and to no more than 48 grams in any one-year period. Also, effective June 8, 2012, on every sale of PSE products from behind the counter, an offer to counsel the purchaser must be given. Pharmacies will need to modify their processes accordingly.

E-Signatures for Non-Controlled Prescriptions Now Acceptable

Electronic prescribing of controlled substances (EPCS) is permitted by the rules promulgated by the Board. However, it is subject to compliance with federal Drug Enforcement Administration (DEA) rules on EPCS, including having the prescriber's and the dispenser's EPCS systems both certified as appropriate systems under DEA law. Until then, many prescriber's prescriptions for controlled and non-controlled substances are being converted from electronic prescriptions by either the prescriber's system, their third-party data intermediary, or the pharmacy's system. In the case of controlled substances, DEA law is clear that a wet signature by the prescriber is required on any written prescription, including faxed or e-faxed prescriptions. However, for non-controlled prescriptions, prescribers requested the Board to consider the electronic or digitized signatures on prescriptions that are faxed or e-faxed to the pharmacy be considered as legally signed prescriptions by the Board. The Board reviewed the issue at its March meeting, and passed a motion to accept e-signatures on non-controlled prescriptions that are faxed or e-faxed to the pharmacy. During discussion of the motion it was explained that this would include "digitized" signatures (a computer-generated copy of the prescriber's written signature stored in his or her prescribing system), and that, just as with oral prescriptions, the pharmacy must have sufficient assurance that the faxed prescription did come from the prescriber and is otherwise a legal prescription.

Animal Drug Product Added as Approved Generic Substitute

West Virginia is an *Orange Book* state for generic substitution. However, the *Orange Book* pertains only to human drugs. As such, representatives of FidoPharm® presented their request to the Board to separately recognize their animal drug product, PetTrust Plus® Chewable Tablets, as an acceptable generic substitute for Tri-Heart Plus® and Heartgard Plus® Chewable Tablets. Based upon the review of the Food and Drug Administration Abbreviated New Animal Drug Application (ANADA) and ANADA process and other materials submitted in support of their request the Board passed a motion to approve the request and add PetTrust Plus Chewable Tablets as a proper generic substitute for Tri-Heart Plus and Heartgard Plus Chewable Tablets under West Virginia law.

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West Virginia Board of Pharmacy

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